CLAIMS

I claim:

1. A method of preparing calibration slides for a cell imaging densitometer, comprising the steps of:

(a) immobilizing cultured cells in a hydrophilic matrix;

(b) placing the matrix in molten paraffin;

(c) cooling the molten paraffin until it solidifies; and

(d) without substantial intervening fixation, sectioning the solidified paraffin containing the immobilized cells into at least one thin slice suitable for optical microscopy.

2. The method of claim 1, wherein the cultured cells are contacted with a tissue fixative prior to immobilization in the hydrophilic matrix.

3. The method of claim 2, wherein step (d) is carried out without any intervening fixation.

4. The method of claim 1, wherein the intervening fixation consists of exposure to normal buffered formalin for about two hours or less.

5. The method of claim 4, wherein the intervening fixation consists of exposure to normal buffered formalin for about one hour or less.

6. The method of claim 5, wherein the intervening fixation consists of exposure to normal buffered formalin for about ten minutes or less.

7. The method of claim 1, further comprising the step of contacting the slice with a first antibody.

8. The method of claim 2, further comprising the step of contacting the slice with a first antibody.

9. The method of claim 7, wherein the first antibody is conjugated to a chromogenic or fluorogenic reagent.

10. The method of claim 8, wherein the first antibody is conjugated to a chromogenic or fluorogenic reagent.

11. The method of claim 7, further comprising the step of contacting the slice with a second antibody having binding affinity for the first antibody.

12. The method of claim 8, further comprising the step of contacting the slice with a second antibody having binding affinity for the first antibody.

13. The method of claim 11, wherein the second antibody is conjugated to a chromogenic or fluorogenic reagent.

14. The method of claim 12, wherein the second antibody is conjugated to a chromogenic or fluorogenic reagent.

15. The method of claim 7, wherein the first antibody is conjugated to biotin.

16. The method of claim 8, wherein the first antibody is conjugated to biotin.

17. The method of claim 15, further comprising the step of contacting the slice with a biotinylated chromogenic or fluorogenic reagent in the presence of avidin or streptavidin.

18. The method of claim 16, further comprising the step of contacting the slice with a biotinylated chromogenic or fluorogenic reagent in the presence of avidin or streptavidin.

19. A method for measuring the amount of a protein of interest in a cell or a cell organelle, comprising the steps of:

(a) affixing said cell to a microscope slide;

(b) staining said cell with an immunohistochemical stain;

(c) measuring with a cell imaging densitometer the area and density of the stain within the cell or cell organelle;

(d) calculating the summed optical density of the stain within the cell or cell organelle; and

(e) converting the summed optical density into the amount of protein of interest, by reference to

(i) a calibration slide prepared according to claim 9 or claim 10, and stained with the same immunohistochemical stain as was used in step (b); and

(ii) the amount of protein of interest actually in the cells or organelles on the calibration slide, as measured by an assay of the protein of interest in a sample of the cells or organelles.

20. The method of claim 19, wherein the protein of interest is a tumor-associated protein.

21. The method of claim 19, wherein the cell is a tumor cell.

22. The method of claim 19, wherein the cell is fixed in a paraffin tissue section.

23. A method of calculating a patient's body burden of a tumor-associated protein of interest, comprising the steps of:

(a) measuring the amount of the protein of interest in one or more cells taken from one or more of said patient's tumors, by the method of claim 21;

(b) converting the amount of protein determined in step (a) into the amount of protein in the tumor from which the cell was obtained; and

(c) adding the amount of protein in each tumor to obtain the total amount of protein in the patient's tumors.

24. A method of calculating the probable clinical outcome of cancer for a patient, comprising the steps of:

(a) providing a statistically-derived continuous function relating the body burden of a tumor-associated protein to clinical outcome, in a population of patients with the same cancer;

(b) measuring the patient's body burden of the tumor-associated protein by the method of claim 23; and

(c) using the continuous function provided in step (a) to calculate the probable clinical outcome.

25. A method of calculating the probable clinical outcome of cancer for a patient, comprising the steps of:

(a) providing a statistically-derived continuous function relating the amount of a tumor-associated protein within tumor cells to clinical outcome, in a population of patients with the same cancer;

(b) measuring the amount of a tumor-associated protein within the patient's tumor cells by the method of claim 21; and

(c) using the continuous function provided in step (a) to calculate the probable clinical outcome.

26. The method of claim 21, wherein the tumor-associated protein is $p53^{mut}$.

27. The method of claim 22, wherein the tumor-associated protein is $p53^{mut}$.

28. The method of claim 23, wherein the tumor-associated protein is $p53^{mut}$.

29. The method of claim 24, wherein the tumor-associated protein is $p53^{mut}$.

30. The method of claim 25, wherein the tumor-associated protein is $p53^{mut}$.

31. A method of selecting a patient for p53-specific therapy, which comprises measuring the amount of $p53^{mut}$ within the patient's tumor cells by the method of claim 26.

32. A method of selecting a patient for p53-specific therapy, which comprises measuring the patient's body burden of $p53^{mut}$ by the method of claim 26.

33. The method of claim 31, wherein the p53-selective therapy is genetic therapy with p53-encoding DNA.

34. The method of claim 32, wherein the p53-selective therapy is genetic therapy with p53-encoding DNA.

35. A method of monitoring the effectiveness or progress p53-specific therapy, which comprises measuring the amount of $p53^{mut}$ within the patient's tumor cells by the method of claim 26.

36. A method of monitoring the effectiveness or progress of p53-specific therapy, which comprises measuring the patient's body burden of $p53^{mut}$ by the method of claim 30.

37. The method of claim 35, wherein the p53-specific therapy is genetic therapy with p53-encoding DNA.

38. The method of claim 36, wherein the p53-specific therapy is genetic therapy with p53-encoding DNA.

39. A method of preparing calibration slides for a cell imaging densitometer, comprising the steps of:

(a) immobilizing cultured cells in a hydrophilic matrix;

(b) placing the matrix in molten paraffin;

(c) cooling the molten paraffin until it solidifies; and

(d) sectioning the solidified paraffin containing the immobilized cells into at least one thin slice.